

Application Number: 10/798,594

Reply To Office Action of NOVEMBER 8, 2005

Amendments to the Specification

Please replace the Abstract {Paragraph [000047]} with the following amended paragraph:

A needle assembly for an intradermal injection device, and a drug delivery device, having which includes a needle cannula ~~having a needle tip~~ and a limiter surrounding the needle cannula and ~~having~~ includes a skin engaging surface on the limiter, wherein ~~the~~ The limiter is moveable from a first position in which an elongate portion of the needle cannula is exposed for access to a medication vial, to a locked second position in which the limiter is not movable from the second position to the first position, ~~and in which~~ In the second position, the needle tip extends beyond the skin engaging surface a distance of about 3 mm or less.

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Please replace the Paragraph [0011] with the following amended paragraph:

[0011] FIG. 1 shows an intradermal injection device 101 comprising a syringe 114 having a syringe body 116 that defines a reservoir 118 within which a drug substance may be held, a plunger 120 disposed in the syringe body 116 and having a flange 122 at a distal end thereof and a stopper 124 at the opposed proximal end thereof, and a needle assembly 102 secured to a distal end of the syringe body 116. An exemplary needle assembly 102 of the type depicted in FIG. 1 is disclosed in U.S. Pat. No. 6,494,865 to Alchas, the entire contents of which is incorporated by reference herein. The needle assembly 102 is specifically designed for making intradermal injections. The needle assembly 102 may carry a needle cannula 104 having a needle tip 106 at a distal end thereof. Alternatively, the needle cannula 104 may be secured directly to the syringe body 116. The needle assembly 102 also includes a penetration limiter 108 having a hub portion 109 that may be secured to the syringe body 116, and a limiter portion 111 that defines a generally flat skin engaging surface 110 at a distal end of the limiter 108. The limiter 108, which generally surrounds the proximal end of the needle 104, permits a certain predetermined length of the needle cannula 104, including the needle tip 106, to protrude beyond the skin engaging surface 110 so that the distance between the needle tip 106 and skin engaging surface 110 limits penetration of the needle tip 106 into the intradermal space of the patient's skin. Preferably, the needle tip 106 of the needle cannula 104 extends beyond the skin engaging surface 110 a distance ranging from approximately 0.5 mm to 3 mm. The needle cannula 104 and skin engaging surface 110 are also arranged with respect to each other in a generally perpendicular relationship that serves to ensure a generally perpendicular relationship between the needle cannula 104 and the patient's skin; such an angular relationship being preferred when making intradermal injections. The skin engaging surface 110 engages the surface of the skin of a patient and limits the penetration depth of the needle tip 106 into the patient's skin. The needle assembly 102 is secured to the syringe 114 via the hub portion 109, which may be fixedly secured to the syringe body 116, or the hub portion 109 may be secured by a Luer fit or equivalent attachment method.

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Please replace the Paragraph [0012] with the following amended paragraph:

[0012] Referring now to FIG. 2, a conventional syringe 114 being filled from a multi-use vial 126 is shown. The vial 126 includes an open end, a rim surrounding the open end and a reduced diameter neck portion adjacent the rim. The vial 124 is typically sealed with an elastomeric septum 128 which includes a portion inserted into the neck of the vial 126 and a planar rim portion which overlies the vial rim. The septum 128 is normally secured to the vial rim with an aluminum collar 130. In FIG. 2, a conventional syringe 114 is being used to access a drug substance contained within the vial 126. The needle 104 in this case is sufficiently long to penetrate the septum 128 to access the drug substance contained in the vial 126.